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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,689	09/29/2003	Jan Andersson	06275-131002	1299
26161	7590	05/15/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			BUNIN, ANDREW M	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 05/15/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,689

Applicant(s)

ANDERSSON ET AL.

Examiner

Andrew M. Bunin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-41 and 55-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-41 and 55-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/066,319.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

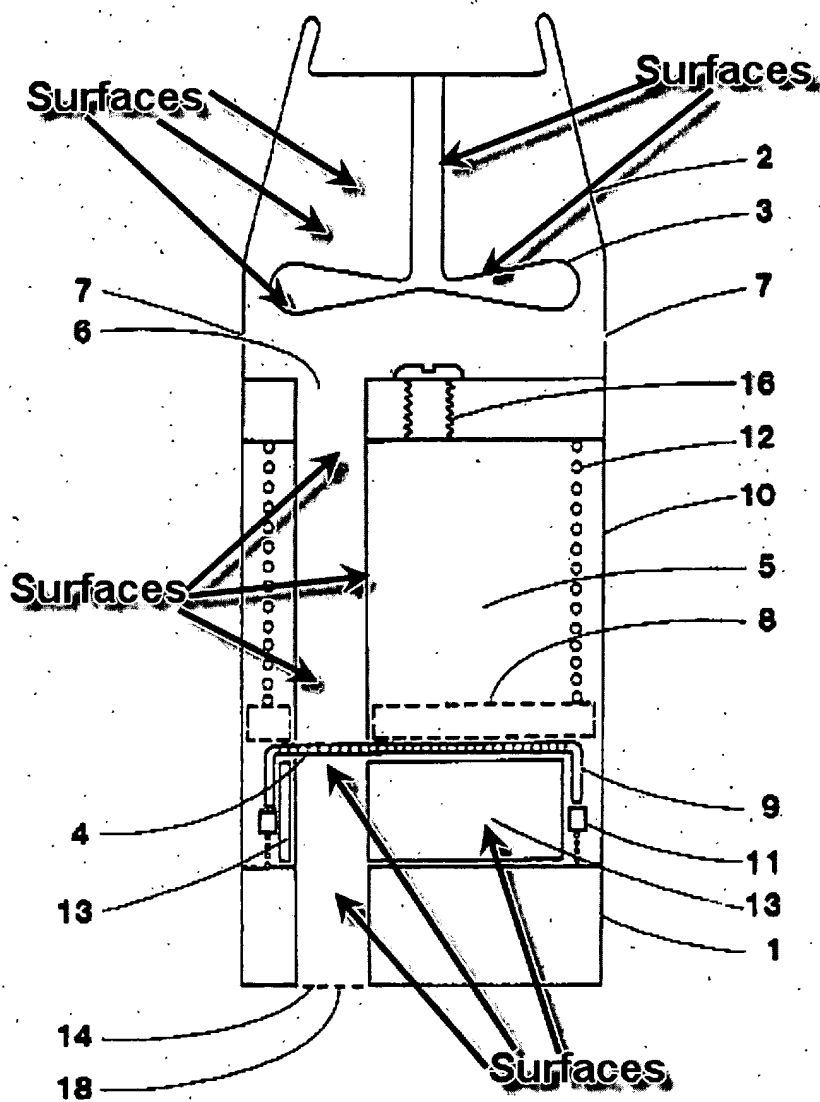
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Wetterlin (US 4524769). Figure 1 discloses a powder inhaler for administering powder by inhalation, comprising a dosing unit 10 for providing a dose of powder and a flow path (7 to 14) downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user. A surface is defined as a "portion of space having length and breadth but no thickness " or "the two-dimensional locus of points located in three-dimensional space" (dictionary.com). Therefore, the plurality of spaces reads on any point within the nozzle 2, anywhere along the flow path, or any section such as the dosing means or membrane that interacts with the flow path, etc. One of the surfaces 4 of the flow path is movable by rotation relative to at least one other of the surfaces of the flow path (column 4, lines 28-32). The inhaler further comprises a powder-dislodging member 3, which is of fixed position relative to at least one of the surfaces of the flow path and is configured on relative movement of one and one other of the surfaces of the flow path in order to contact a surface of the flow path such as to dislodge powder accumulated thereon, wherein the powder dislodging member 3

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comprises a scraper (column 2, lines 65-68) (column 3, lines 3-7). The rotary 3 has blades that act as a scraper dislodging powder that has accumulated in any of the surfaces within section 2 and around conduit 6. Wetterlin teaches how the rotating means 3 disrupts the aggregate particles; therefore, it is capable of dislodging powder accumulated in the inhaler. In addition, each blade of the rotating means reads on the definition of a scraper (a tool that scrapes).

Wetterlin continues to teach one of the surfaces 4 of the flow path as being movable relative to at least one other of the surfaces of the flow path and the scraper 3 is of fixed position relative to the at least one other of the surfaces of the flow path as shown below. The flow path includes a chamber 5 that includes an inlet and an outlet and at least one of the surfaces of the flow path defines part of the chamber 28 as shown in Figure 1. In addition, figure 1 discloses at least one of the surfaces of the flow path defining part of opposed surfaces of the chamber 5. Chamber 5 is a storage chamber for storing a plurality of doses of powder and includes a filling inlet in one of the opposed surfaces of the chamber, and a plug 16 for sealing the filling inlet of the storage chamber, which plug includes a scraper. Figure 1 discloses an inhaler comprising a mouthpiece 2, which includes at least one of the surfaces of the flow path.



Prior Art- US 4524769

Claims 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hallworth et al. (US 3858583). Figure 1 discloses a powder inhaler for administering powder by inhalation, comprising a dosing unit 13 for providing a dose of powder and a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on

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inhalation by a user. One of the surfaces (blade of rotor) of the flow path is movable relative to at least one other of the surfaces of the flow path. The inhaler further comprises a powder-dislodging member 5, which is of fixed position relative to at least one of the surfaces of the flow path and is configured on relative movement of one and one other of the surfaces of the flow path in order to contact a surface of the flow path such as to dislodge powder accumulated thereon, wherein the powder dislodging member 5 comprises a scraper. Hallworth teaches how the "rotor 5 is arranged to brush the end of the capsule 13" and cause an efficient dispersion of the powdered medicament into the air." Therefore, the rotor is capable of dislodging powder accumulated in the inhaler. In addition, each blade of the rotator reads on the definition of a scraper. One of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path and the scraper 5 is of fixed position relative to the at least one other of the surfaces of the flow path as shown in figure 1. The flow path includes a chamber 2 that includes an inlet and an outlet and at least one of the surfaces of the flow path defines part of the chamber 2 as shown in Figure 1. In addition, figure 1 discloses at least one of the surfaces of the flow path defining part of opposed surfaces of the chamber 2. Chamber 2 is used for storing a plurality of doses of powder and includes a filling inlet in one of the opposed surfaces of the chamber, and a plug 9 for sealing the filling inlet of the storage chamber, which plug includes a scraper. Figure 1 discloses an inhaler comprising a mouthpiece 4, which includes at least one of the surfaces of the flow path.

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It is noted that applicant's specification does not set forth the feature of the scraper or brush as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. In addition, applicant states that the dislodging member may also function as a piezoelectric element (paragraph 52). Therefore, the applicant hasn't shown any criticality for the dislodging member as a brush or scraper. Any device that meets the criteria for the dislodging member within the inhalation device may be substituted for the scraper or brush.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55, 57-59, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wetterlin/Hallworth et al. in view of Ambrosio et al. (US 5,829,434). Wetterlin/Hallworth et al. disclose everything except a housing that includes a screw thread and a cap for covering at least the mouthpiece, where the cap includes a screw thread for engaging the screw thread on the housing. In addition, Wetterlin/Hallworth et al. also doesn't disclose that the mouthpiece and cap are configured such that at least part of the mouthpiece is rotated relative to the housing on one of screwing or unscrewing the cap where part of the mouthpiece remains substantially in a fixed position relative to the housing as the cap is screwed or unscrewed. However,

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Ambrosio et al. teaches the use of a housing 120 which includes a screw thread 352 and a cap 520 for covering at least the mouthpiece 440, includes a screw thread 520 for engaging the screw thread on the housing as shown in figure 1 and 2. Therefore, it would have been obvious to one of ordinary skill in the art to combine the cap screwing means taught by Ambrosio et al. in combination with the inhaler of Wetterlin/Hallworth et al. in order to cover the inhaler to keep it isolated from external dirt and other debris.

Ambrosio et al. teaches a cap 520 having ribs 534 and 536 that fall into the recesses 164 and 166 of housing 120. Ambrosio et al. states, "Thus, closing rotation of closure cap 520 causes the same rotation of driving body 120, and thereby of venture conduit 64 relative to metered dose hole 184" (column 24, lines 36-39). Ambrosio et al. disclose the claimed invention except for the mouthpiece and cap are not configured such that at least part of the mouthpiece is rotated relative to the housing on one of screwing or unscrewing the cap where part of the mouthpiece remains substantially in a fixed position relative to the housing as the cap is screwed or unscrewed. It would have been obvious to one of having ordinary skill in the art at the time the invention to place the ribs 534 and 536 at a location level with the mouthpiece and place the recesses on the mouthpiece section 440 of the housing 120, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As for claims 57 and 59, Ambrosio et al. teach a cap 520 having ribs 534 and 536 that fall into the recesses 164 and 166 of housing 120. Ambrosio et al. states, "Thus, closing rotation of closure cap 520 causes the same rotation of driving body 120, and thereby of venture conduit 64 relative to metered dose hole 184" (column 24, lines

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36-39). Ambrosio et al. discloses the claimed invention except for the mouthpiece and cap each include parts which engage on the one of screwing of unscrewing the cap so as to rotate part of the mouthpiece relative to the housing. It would have been obvious to one of having ordinary skill in the art at the time the invention to place the ribs 534 and 536 at a location level with the mouthpiece and place the recesses 164 and 166 on the mouthpiece section 440 of the housing 120, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As for claim 58, wherein the engaging parts comprise at least one biased member 534 and at least one recess 164, which at least one biased member 534 is configured to engage at least one recess on the one of screwing or unscrewing the cap 520. Ambrosio et al. states, "due to the resilience of the plastic elements, radially extending ribs 160 of upper securing walls." (column 22, lines 60-62) Therefore, it would have been obvious to one of ordinary skill in the art to use the resilient material of the ribs 160 for ribs 534 and 536.

Claims 56 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wetterlin/Hallworth et al. and Ambrosio et al. in view of Andersson et al. (US 6257232). US 6257232 to Andersson et al., applicant describes Figures 1-4 as admitted prior art. Given this admission, the following rejection based on 103 is considered appropriate. Andersson et al. disclose a housing 6 that includes a rotatable grip portion 8 that is rotated to provide a dose of powder for inhalation in the same sense as that in which the cap is rotated to rotate the part of the mouthpiece relative to

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the housing. Andersson et al. states, "the housing unit 16 is rotated by rotating the grip portion 8 in the counter-clockwise sense...grip portion 8 comprises a resilient member which is configured to engage with an axially-directed surface 60a...so as to rotate the dosing unit 16" (column 2, lines 29-37). As for claim 56, Andersson et al. has disclosed at least one other of the surfaces of the flow path as being in a fixed position relative to the housing 6 such that at least one of the surfaces of the flow path is moved relative to at least one other of the surfaces of the flow path on rotation of part of the mouthpiece 2 relative to the housing 6 as shown figure 3 and 4. The divider 14 in figure 4 allows the mouthpiece 2 to be capable of rotating in the manner stated above. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Wetterlin/Hallworth et al. to include a rotating grip portion for easily providing a dose of powder before inhalation as well as a rotating mouthpiece that allows a user to easily take off the mouthpiece for cleaning purposes.

As for claim 61, Ambrosio et al. teaches a rotation resistance mechanism 494 for providing resistance to relative rotation of part of the mouthpiece 440 and the housing 120 as shown in figure 57.

As for claim 62, Ambrosio et al. discusses how the "closing rotation of closure cap 520 causes the same rotation of driving body 120, and thereby venture conduit 64 relative to metered dose hole 184, to the store position, 180 degrees out of alignment" (column 24, lines 36-39). Therefore, it can be considered obvious that the rotation of the mouthpiece relative to the housing by screwing or unscrewing the cap must be of forces greater than that required to rotate the cap 520.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wetterlin/Hallworth et al. in view of Ambrosio et al. and further in view of Wetterlin (US 5983893). Ambrosio et al. has disclosed everything except for the rotation mechanism of claim 63 comprising a ratchet mechanism. Wetterlin teaches a ratchet mechanism for an inhalation device in figure 1 and states, "the maneuvering unit 13 is rotated...means could be provided as a ratchet mechanism" (column 3, lines 61-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the engaging rotation mechanism taught by Ambrosio et al. with the ratchet mechanism as taught by Wetterlin.

Lastly, it can be considered obvious that the rotation of part of the mouthpiece relative to the housing as taught by Ambrosio et al. would cause no damage thereto. It is considered common sense that an invention would take into consideration that a cap would cause no damage when being screwed or unscrewed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the screwing cap technology taught by Ambrosio et al. with the inhaler disclosed by Wetterlin/Hallworth et al. in order for the inhaler to be effectively closed off from allowing external dirt or material from entering the inhalation device.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-4, 18, 23, 30, and 39 of U.S. Patent No. 6,257,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because "movable member" is used instead of powder dislodging member. In addition, it states in claim 34 that the powder-dislodging member comprises one of a scraper or a brush, which is not stated in the claims of the patent. However, Patent #6257232 discloses a scraper that reads on the claims pertaining to the movable member. In addition, claim 40 states a plug for sealing the filling inlet of the storage chamber, which is also not stated in the claims of the patent. However, as stated above in the 102b rejection, the applicant has considered the plug common in the related prior art in order to seal a filling inlet of a storage chamber.

Claims 55 and 59-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-4 of U.S. Patent No. 6,446,626 in view of Ambrosio et al. (US 5,829,434). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent don't state a mouthpiece and cap configured such that part of the mouthpiece is rotated relative to the housing on one of screwing or unscrewing the cap.

However, this limitation is considered obvious in view of Ambrosio et al. (US 5687710) as discussed in the 103a rejection above.

Response to Arguments

Applicant's arguments filed 2/27/06 have been fully considered but they are not persuasive. In response to applicant's arguments of a powder dislodgement, examiner notes that the powder-dislodging member 3, which is of fixed position relative to at least one of the surfaces of the flow path and is configured on relative movement of one and one other of the surfaces of the flow path in order to contact a surface of the flow path such as to dislodge powder accumulated thereon, wherein the powder dislodging member 3 comprises a scraper (column 2, lines 65-68) (column 3, lines 3-7). The rotary 3 has blades that act as a scraper dislodging powder that has accumulated in any of the surfaces within section 2 and around conduit 6. Wetterlin explicitly states that the rotating means 3 disrupts the aggregate particles of an active compound that might have been formed. Therefore, rotating means 2 is capable of dislodging powder accumulated in the inhaler. In addition, each blade of the rotating means reads on the definition of a scraper (a tool that scrapes).

In addition, Hallworth discloses a similar device with a "rotor 5 [that] is arranged to brush the end of the capsule 13" and cause an efficient dispersion of the powdered medicament into the air." Therefore, the rotor is capable of dislodging powder accumulated in the inhaler.

In response to arguments related to a flow path having at least one surface that is movable relative to at least one other surface of the flow path, examiner notes that a surface is defined as a "portion of space having length and breadth but no thickness " or "the two-dimensional locus of points located in three-dimensional space" (dictionary.com). Therefore, the plurality of spaces reads on any point within the nozzle 2, anywhere along the flow path, or any section such as the dosing means or membrane that interacts with the flow path, etc. Wetterline discloses one of the surfaces 4 of the flow path is movable by rotation relative to at least one other of the surfaces of the flow path (column 4, lines 28-32). In addition, flow path can be defined as any part of the device wherein the powder or some gas flows through it. For example, Hallworth et al. discloses a rotor that rotates gas and/or powder above capsule. Therefore, the rotor can be broadly interpreted as a surface that is movable relative to at least one other surface (capsule or sidewall next to capsule) of the flow path.

Lastly, examiner maintains obviousness-type double patenting between instant application and patent number 6,527,232. Patent number 6,527,232 claims a movable member for inhibiting accumulation of powder on a surface of the flow path and the member interrupting the stream of air can be broadly interpreted as a dislodging member contacting a surface of an airflow path being capable of dislodging already accumulated powder. In response to applicant's argument that the movable member cannot dislodge already accumulated powder, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention

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and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 4907583, US 4805811, US 4667668, US 6240918, US 5243970, US 5687710, US 6102036, US 5655523, US 5341800, and US 6325061

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AMB
5/10/06


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